Oey, Jan
_____

From: Jill Schultz [jill.schultz@Covance.Com]
Sent: Friday, November 02, 2001 11:55 AM
To: Robin.D.Kinser@pmusa.com
Cc: Jan.Oey@pmusa.com; libby@truman.edu
Subject: RE: Nicotine Glucuronide validation data

Thank you. I will arrange a call for the week of 11/12 when Mark returns. Jill

>>> <Robin.D.Kinser@pmusa.com> 11/2/01 10:35:48 AM >>>
Dear Jill--

You are authorized to proceed with analysis of the glucuronides of
nicotine and its metabolites , based on the interim validation data
below.
I am authorizing you to proceed despite the failure of nicotine
glucuronide
in freeze/thaw and room temperature stability testing, largely because
the
cotinine glucuronide did pass short term stability testing, and my
memory of
previous indications of a systematic nicotine contaminant. I am
concerned,
however, about this apparent nicotine contamination in the SPE
cartridges,
and the impact this may have on our measurements of nicotine and
metabolites
in non-smokers.

After Mark has returned and re-grouped, let's plan a discussion
call
to identify the questions which have arisen during validation and
begin
preparing action plans to address those issues.

--Robin
> ----Original Message----
> From: Jill Schultz [SMTP:jill.schultz@Covance.Com]
> Sent: Friday, October 19, 2001 10:01 AM
> To: Holt.Klausvon@pmintl.ch; kuhl.peter@pmintl.ch;
> rustemeier.Klaus@pmintl.ch; Schepers.Georg@pmintl.ch;
> Stabbert.Regina@pmintl.ch; tricker.anthony@pmintl.ch;
> Hans-Juergen.Roethig@pmusa.com; Jan.Oey@pmusa.com;
> robin.d.kinser@pmusa.com
> Subject: Nicotine Glucuronide validation data
>
> Attached are the tabulated validation data for the glucuronide assay
and
> summary sheets. These data are not 100% QC checked at this stage,
hence
> they may be subject to minor change. Please review and contact me
with
> any questions or your authorization to proceed with sample analysis.
>
> Mark had the following comments to add regarding these data:
>
> Water blank samples containing internal standard (technically
the

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